REMARKS

A Petition for Extension of Time is being concurrently filed with this Amendment. Thus, this Amendment is being timely filed.

Applicants respectfully request the Examiner to reconsider the present application in view of the following remarks.

Status of the Claims

Claims 8-17 are pending in the present application. Claims 1-7 were previously canceled without prejudice or disclaimer of the subject matter contained therein. In the present response, no claims are being amended, canceled or added. Thus, a listing of the claims is not needed.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, Second Paragraph

Claims 8-14 and 17 stand rejected under 35 U.S.C. § 112, second paragraph, for asserted lack of definiteness as stated in paragraph 4 of the Office Action. Applicants respectfully traverse, and reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner states: "It is unclear what types of medicines are encompassed by 'Kampo medicines;' thus, the metes and bounds of the claims are unclear". However, Applicants respectfully submit that the present specification as well as the state of the art adequately define such claim language and the burden of proving patentability has not shifted to Applicants.

First, Applicants respectfully refer the Examiner to page 1, the "Technical Field" section and page 5, lines 11-15 of the present specification, wherein it is described how the Kampo medicinal extract powder is defined and obtained ("The Kampo medicinal extract powder used in the present invention is one obtained by decocting a general Kampo medicinal formulation and concentrating and drying the decoction."). Further, lines 15+ of page 5 of the specification describes the various types of this powder, wherein one of skill in the art would understand the meaning of a Kampo medicinal extract powder based on such Examples.

Regarding the state of the art, Applicants respectfully refer the Examiner to known literature as well as the USPTO's already established position. For instance, please refer to claim 1 (column 10) of U.S. Patent No. 5,318,798 (this reference is even cited in paragraphs **5-6** of the Office Action). This page of the '798 patent is attached.

In view of the above comments, Applicants also submit that the burden of proving patentability has not shifted to Applicants: "The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention on any ground is always upon the examiner." *Ex parte* Parks, 30 USPQ2d 1234, 1236 (citing In *re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992)); *see also In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984).

In addition, if the question here is the breadth of the term "Kampo medicine," Applicants note that the breadth of the claim does not automatically equate to indefiniteness with supporting U.S. case law. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (BNA) (CCPA 1971); *see also* M.P.E.P. § 2173.04. Further, claim language must be read in light of the specification as it would be interpreted by one of ordinary skill in the art. *In re Johnson and Farnham*, 194 USPQ 187, 194 (CCPA 1977). As pointed out above, those skilled in the art will be able to determine

immediately from Applicants' detailed specification the meaning of a Kampo medicine, how it is obtained, and even see specific examples of such a medicine, as necessary to practice the invention. Thus, Applicants submit that the subject matter embraced by claims is definite and that the claims set out and circumscribe a particular area with a reasonable degree of precision and particularity. Withdrawal of this rejection is respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 8, 10, 12 and 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over T. Uchida *et al.* '798 (U.S. Patent No. 5,318,798) in view of JP '122 (JP 61033122 A) and JP '504 (JP 11060504) (see paragraph 5 of the Office Action).

Also, claims 9, 11, 13, 14, 16 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Uchida '798 in view of JP '122 and JP '504 as applied above, and further in view of JP '416 (JP 5612416 A).

Applicants respectfully traverse, and reconsideration and withdrawal of both rejections are respectfully requested. Applicants do not concede that a *prima facie* case of obviousness has been established with respect to either rejection.

(A) Unexpected Results for the Claimed Invention

Applicants respectfully submit that the present invention has achieved unexpected results, whereby such results rebut any asserted *prima facie* case of obviousness (whether based on Uchida '798, JP '122, JP '504 and/or JP '416 or any other reference or combinations thereof). *See In re Corkill*, 711 F.2d 1496, 226 USPQ (BNA) 1005 (Fed. Cir. 1985); *see also In re*

Papesch, 315 F.2d 381, 137 USPQ (BNA) 43 (CCPA 1963); *In re Wiechert*, 370 F.2d 927, 152 USPQ (BNA) 247 (CCPA 1967). As stated in M.P.E.P. § 2144.09 (see section entitled "*Prima Facie* Case Rebuttable By Evidence of Superior or Unexpected Results"), any rejection under 35 U.S.C. § 103(a) may be rebutted by a sufficient showing of unexpected results for the present invention.

Applicants note Tables 1-2 in the present specification (at pages 17 and 19, respectively). Comparative Example 1-2 and Comparative Example 4-1 contain sodium hydrogen carbonate. In the Office Action, the primary reference of Uchida '798 is cited for its disclosure of a Kampo medicine, and the secondary reference of JP '504 is cited for the disclosure of sodium hydrogen carbonate. In this regard, the comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. *See* M.P.E.P. §§ 716.02(b) and 716.02(e); *see also In re Fenn et al.*, 208 USPQ 470 (CCPA 1981).

With respect to the mentioned Comparative Examples, Applicants note the inferior properties thereof, especially when compared to the present invention. In particular, Applicants respectfully refer the Examiner to Examples 1 and 4 which are similar to Comparative Examples 1-2 and 4-1 but the inventive Examples contain cellulose glycolate. For example, as shown in Table 1, Example 1 has unexpectedly superior disintegration time versus that of Comparative Example 1-1 or 1-2. Applicants note that superiority can establish unexpected results. *See In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987).

The secondary reference of JP '122 is cited for its disclosure of cellulose glycolate. In this regard, Applicants respectfully refer the Examiner to Comparative Examples 1-3 and 4-4 that contain cellulose glycolate, in comparison to Inventive Examples 1 and 4. Again, the present

invention achieves unexpected and superior results over the Comparative Examples. For instance, Applicants note the dissolution rates in Table 2 between these compositions.

Therefore, even if the Examiner has hypothetically established a *prima facie* case of obviousness, a point not conceded by Applicants, the unexpectedly superior results according to the present invention rebut such a hypothetical case of obviousness. For instance, Tables 1 and 2 in the present specification provide objective evidence proving the unexpectedly superior results according to the present invention. It is clear from Applicants' experimental data that the present invention has achieved synergistic and superior effects based on using sodium hydrogen carbonate and cellulose glycolate as instantly claimed (see, e.g., claim 8).

Further, Applicants further submit that the § 103(a) rejections are overcome because evidence of unexpected results is in the present specification and it is improper to not consider such evidence of patentability for the present invention. *See In re Soni*, 54 F.3d 746, 34 U.S.P.Q.2d 1684 (Fed. Cir. 1995) (error not to consider evidence in the specification); M.P.E.P. § 2144.08(II)(B).

Reconsideration and withdrawal of the outstanding rejections are therefore respectfully requested.

(B) *Not All Requirements for a Prima Facie Case of Obviousness Satisfied*

Applicants note the Examiner's reasons for combining the cited references. For instance, the Examiner cites JP '122 and JP '504 and states better disintegration as the reasons for combining the references (see, e.g., the paragraph bridging pages 3-4 of the Office Action).

Applicants respectfully disagree in that one of ordinary skill in the art would lack the requisite motivation to combine such references in an effort to achieve the present invention.

First, the present specification already acknowledges that the Kampo medicinal extract powder itself is known in the art, and that the problems in the art include, e.g., unsatisfactory dissolution of the active ingredient(s) and disintegration of the tablets (see page 2, lines 10-17). In this regard, the cited references must suggest the desirability of the modification. *In re Brouwer*, 37 USPQ2d 1663, 1666 (Fed. Cir. 1995). There is no disclosure of better disintegration of the instantly claimed combination of ingredients. Instead, for example, JP '122 discloses a "drug" generically without any reference to a Kampo medicinal extract powder. Thus, while a reference need not expressly teach that the disclosure contained therein should be combined with another, *see Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997), the showing of combining references "must be clear and particular". *See In re Dembiczak*, 175 F.3d 994, 998, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Here, there is no guidance in any of the cited references to achieve the formulations as presently claimed.

Thus, at least the requisite motivation is lacking and a *prima facie* case of obviousness has not been established. *See In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Further, Applicants note the experimental results in the present specification as discussed. Evidence of such results shows the unexpected, superior and beneficial properties of the present invention. Thus, because the results are unexpected and superior, there can be no motivation. *See* M.P.E.P. § 2144.09.

Regarding the Examiner's comments at the bottom of page 5 of the Office Action, no scientific evidence has been presented to show the instantly claimed amounts are a "result

effective parameter" or a matter of optimization. Regarding the sentence bridging pages 5-6 of the Office Action, Applicants note the discussion above regarding unexpected results for the presently claimed invention.

Based on the above, reconsideration and withdrawal of both rejections are respectfully requested.

Conclusion

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez (Reg. No. 48,501) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Attachment: Columns 9-10 of USPN 5,318,798

TEST EXAMPLE 2

The procedure of Example 2 was repeated except that no magnesium stearate was added to the extract granules to obtain Sho-saiko-to hard capsules each weighing 590 mg (Comparative Capsule 2).

The dissolution times of Invention Capsule 2 obtained in Example 2 and Comparative Capsule 2 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 2 was 80 minutes while that of Invention Capsule 2 was 15 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 3

The procedure of Example 3 was repeated except that no magnesium stearate was added to the extract granules to obtain Ninjin-to hard capsules each weighing 404 mg (Comparative Capsule 3).

The dissolution times of Invention Capsule 3 obtained in Example 3 and Comparative Capsule 3 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 3 was 52 minutes while that of Invention Capsules 3 was 18 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 4

The procedure of Example 5 was repeated except that no magnesium stearate was added to the extract granules to obtain Mao-bushi-saishin-to hard capsules each weighing 320 mg (Comparative Capsules 4).

The dissolution times of Invention Capsule 4 obtained in Example 5 and Comparative Capsule 4 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 4 was 85 minutes while that of Invention Capsule 4 was 14 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 5

The procedure of Example 6 was repeated except that no magnesium stearate was added to the extract granules to obtain Anchu-san hard capsules each weighing 321 mg (Comparative Capsules 5).

The dissolution times of Invention Capsule 5 obtained in Example 6 and Comparative Capsule 5 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 5 was 50 minutes while that of Invention Capsule 5 was 17 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 6

The procedure of Example 7 was repeated except that compression-molding was not conducted to obtain Keishi-bukuryo-gan capsules each weighing 300 mg (Comparative Capsule 6).

The dissolution times of Invention Capsule 6 obtained in Example 7 and Comparative Capsule 6 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 6 was longer than 60 minutes while that of Invention Capsule 6 was 8 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 7

The procedure of Example 8 was repeated except that no magnesium stearate was added to the extract granules to obtain Byakko-ka-ninjin-to capsules each weighing 278 mg (Comparative Capsule 7).

The dissolution times of Invention Capsule 7 obtained in Example 8 and Comparative Capsule 7 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 7 was 50 minutes while that of Invention Capsules 7 was 20 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 8

The procedure of Example 9 was repeated except that compression-molding was not conducted to obtain Shakuyaku-kanzo-to capsules each weighing 340 mg (Comparative Capsule 8).

The dissolution times of Invention Capsule 8 obtained in Example 9 and Comparative Capsule 8 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 8 was 60 minutes while that of Invention Capsule 8 was 7 minutes, which indicated that the latter quickly liberated the active ingredient.

TEST EXAMPLE 9

The procedure of Example 10 was repeated except that compression-molding was not conducted to obtain Sairei-to capsules each weighing 315 mg (Comparative Capsule 9).

The dissolution times of Invention Capsule 9 obtained in Example 10 and Comparative Capsule 9 were measured by the same method as in Test Example 1. As a result, it was confirmed that the dissolution time of Comparative Capsule 9 was longer than 60 minutes while that of Invention Capsule 9 was 11 minutes, which indicated that the latter quickly liberated the active ingredient.

According to the present invention, Kampo medicine hard capsules having a high Kampo medicine extract content and showing good dissolution properties, with the elution time ($T_{75\%}$) being not longer than 30 minutes when measured according to the dissolution test (paddle test) specified in the 12th Edition of Pharmacopoeia of Japan, can be obtained.

While the present invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to include all such alternatives, modifications and variations as set forth within the spirit and scope of the appended claims.

What is claimed is:

1. A process for producing Kampo medicine hard capsules, which comprises compacting Kampo medicine extract powder, mixing magnesium stearate with the compacted Kampo medicine extract powder and filling the mixture into gelatin hard capsules.

2. A process as in claim 1, wherein the weight ratio of said magnesium stearate to said compacted Kampo medicine extract powder ranges from 0.5/100 to 3/100.

3. A process as in claim 1, wherein said Kampo medicine is selected from the group consisting of Orengedoku-to, Sho-saiko-to, Ninjin-to, San'o-shashin-to, Mao-bushi-saishin-to, Anchu-san, Keishi-bukuryo-gan, Byakko-ka-ninjin-to, Shakuyaku-kanzo-to and Sairei-to.

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